

# Exhibit 15

*United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.*

Civil Action No. 07-10248-PBS

Exhibit to the August 28, 2009 Declaration of James J. Fauci In Opposition To  
Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc.  
Local Rule 56.1 Statement of Undisputed Material Facts  
in Support of Their Motion For Summary Judgment

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UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

-----X  
IN RE: PHARMACEUTICAL ) MDL NO. 1456  
INDUSTRY AVERAGE WHOLESALE ) CIVIL ACTION  
PRICE LITIGATION ) 01-CV-12257-PBS  
-----X

THIS DOCUMENT RELATES TO )  
United States of America, et al,) Judge Patti B.  
Ven-a-Care of the Florida Keys, ) Saris  
Inc., )  
vs. )  
Boehringer Ingelheim, Corp., ) Chief Magistrate  
et al. ) Judge Marianne B.  
Civil Action 07-10248-PBS ) Bowler  
-----X

(Cross-caption appears on following page)

VIDEOTAPED DEPOSITION OF SHELDON BERKLE

VOLUME I

Naples, Florida

Friday, October 31, 2008

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1 IN THE COURT OF THE SECOND JUDICIAL CIRCUIT

2 IN AND FOR LEON COUNTY, FLORIDA

3 -----X

4 THE STATE OF FLORIDA ex rel. )

5 VEN-A CARE OF THE FLORIDA KEYS, )

6 INC., a Florida Corporation, by )

7 and through its principal )

8 officers and directors, ZACHARY )

9 T. BENTLEY and T. MARK JONES )

10 Plaintiffs, ) CIVIL ACTION

11 vs. ) NO. 98-3032A

12 BOEHRINGER INGELHEIM CORPORATION, )

13 et al. )

14 Defendants. )

15 -----X

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1 A. Yes, there was.

2 Q. When was that?

3 A. It was November 1994.

4 Q. And when did you stop working for  
5 Boehringer Ingelheim's American operations?

6 A. The end of 2003.

7 Q. Upon transfer to the U.S., which  
8 specific entity did you work for?

9 A. BIPI.

10 Q. BIPI. What was your position there?

11 A. Executive vice president.

12 Q. Executive vice president.

13 Did you have -- Did you have a position  
14 at any other Boehringer Ingelheim entities in  
15 America at that time?

16 MR. GASTWIRTH: Objection to form.

17 THE DEPONENT: I was a vice president  
18 for BI Corporation.

19 BY MR. FAUCI:

20 Q. Is it okay if we refer to that as BIC?

21 A. Sure.

22 Q. What about a company known as Roxane

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1 Laboratories, did you have a position with them?

2 MR. GASTWIRTH: Objection to form.

3 THE DEPONENT: No.

4 BY MR. FAUCI:

5 Q. Can you describe in general the  
6 business of BIPI in the 1994 time frame. By  
7 business I mean, among other things, what types  
8 of products was the company marketing or selling?

9 A. Again, it was involved in the research;  
10 basic research, clinical research and marketing  
11 sales of human pharmaceuticals. It was a  
12 relatively smaller company in the U.S.  
13 pharmaceutical business. And we were involved in  
14 a couple therapeutic areas at that point,  
15 respiratory medicine predominantly.

16 Q. Were most of BIPI's products branded  
17 drugs or generic drugs?

18 A. Branded drugs.

19 Q. Can you describe the business of BIC at  
20 about the same time, the 1994 time frame.

21 A. My understanding of what BIC was was  
22 really as a holding company for the U.S.

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1 Q. Can you tell me what the difference is  
2 between a multi-source or --

3 MR. GASTWIRTH: Just hold on for one  
4 second.

5 MR. FAUCI: Sure.

6 MR. GASTWIRTH: Okay. Thanks.

7 BY MR. FAUCI:

8 Q. Can you tell me the difference between  
9 a multi-source or generic product and a branded  
10 generic product.

11 A. Again, my understanding is a multi-  
12 source product is a product in which there are  
13 several companies marketing the same chemical  
14 entity with really no differentiation in terms of  
15 the quality aspects of those drugs.

16 Branded generics in my estimation is  
17 then again not so different in the sense that  
18 these products are still marketed by multiple  
19 companies; however, there is a brand name  
20 attached to that generic drug and there is an  
21 attempt to try to differentiate those branded  
22 generics from each other.

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1 Q. I believe your testimony earlier was  
2 that Roxane was not included within the business  
3 unit; is that correct?

4 A. I believe I said that it was a separate  
5 division.

6 Q. Can you elaborate what you mean by  
7 that.

8 A. Roxane was a separate business entity.  
9 They had their own budgets, their own plans. Any  
10 involvement that I had was really on a strategic  
11 level with Roxane.

12 Q. So is it your testimony that the  
13 business unit was just limited to BIPI?

14 A. The business unit was primarily BIPI  
15 plus a strategic oversight of Roxane, but Roxane  
16 had its own management team and it was  
17 responsible for the annual budgets, marketing  
18 plans, day-to-day operations.

19 Q. But at least on a strategic level -- Is  
20 it fair to say that on a strategic level Roxane  
21 sat within the business unit?

22 MR. GASTWIRTH: Objection to form.

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1 THE DEPONENT: I don't think I would  
2 use the term "sat." They had a separate physical  
3 presence, separate facilities. And within the  
4 strategic oversight, yes.

5 BY MR. FAUCI:

6 Q. What is OPINA?

7 A. OPINA is an acronym that stood for the  
8 optimization of the pharmaceutical business  
9 within North America.

10 Q. The two -- I'm going to read again just  
11 from the end of that paragraph. It says, The two  
12 leading entities, BIPI and Roxane -- I'm sorry,  
13 I'm going to go back a little bit before.

14 Of primary importance to this position  
15 will be, and then it says among other things, the  
16 maximizing of synergies of the two leading  
17 entities, BIPI and Roxane. Were there synergies  
18 between BIPI and Roxane?

19 A. Certainly not -- not at the -- not when  
20 I first came in '94. There really were two  
21 separate businesses.

22 Q. Did you view as one of your goals when

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1 you were hired to maximize synergies between the  
2 two companies?

3 A. I -- Again, I -- Certainly at that  
4 point in time my primary focus was on building  
5 the branded human pharmaceutical business within  
6 BIPI. And certainly one of my -- one of my  
7 objectives was to look down the road as to  
8 whether there were, in fact, any synergies  
9 between the BIPI operation and the Roxane  
10 operation.

11 Q. And down the road were there any  
12 synergies that could be exploited or --

13 A. Yeah. We --

14 MR. GASTWIRTH: Objection to form.

15 THE DEPONENT: We certainly did look at  
16 certain things where we were able to create some  
17 synergies, yes.

18 BY MR. FAUCI:

19 Q. Was this a -- a goal that-- was one of  
20 the goals that you were hired for, to look into  
21 improving the synergies or exploiting or finding  
22 synergies between these companies?

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1 MR. GASTWIRTH: Objection to form.

2 THE DEPONENT: The primary reason why I  
3 was brought to the U.S. was really to grow the  
4 branded pharmaceutical business within BIPI.

5 BY MR. FAUCI:

6 Q. That was the primary reason?

7 A. Right. Primary reason.

8 Q. Was coordinating or improving upon the  
9 synergies between BIPI and Roxane a reason that  
10 you were hired?

11 A. Yes.

12 Q. If you turn to the next page of Exhibit  
13 2. Do you see where it says basic  
14 responsibilities, essential functions?

15 A. Yes, I do.

16 Q. Can you read into the record the third  
17 bullet point.

18 A. The one that begins with "insures  
19 optimization"?

20 Q. That's correct.

21 A. Sure. Insures optimization of  
22 performance in the U.S. through the development

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1 and direction of innovative strategies and  
2 tactics for BIPI and RLI, including prescription  
3 OTC switches and activities to defend brand name  
4 products from generic erosion.

5 BY MR. FAUCI:

6 Q. Is RLI Roxane?

7 A. Yes, it is.

8 Q. It's okay if we refer to both terms  
9 interchangeably today, RLI, Roxane, they both  
10 mean Roxane Laboratories?

11 A. Yes.

12 Q. What are RX/OTC switches?

13 A. Again, that refers to products that are  
14 originally prescription drugs, drugs that must be  
15 prescribed by a physician. And sometimes when  
16 drugs have been on the market for a long period  
17 of time, have established a solid safety record,  
18 you can approach the FDA and determine if you  
19 can, in fact, transition that product or those  
20 products from a prescription basis to over-the-  
21 counter basis so that you can buy them in the  
22 pharmacy without a prescription.

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1 THE DEPONENT: It's possible.

2 BY MR. FAUCI:

3 Q. Do you have any reason to believe it  
4 wasn't sent to Roxane employees?

5 A. I don't know whether it was or wasn't  
6 to be honest with you.

7 Q. Do you see at the second page that this  
8 document was signed by--I might mispronounce his  
9 name--Werner Gerstenberg?

10 A. Yes. And that's correct by the way.

11 Q. Thank you.

12 Who is Mr. Gerstenberg?

13 A. Mr. Gerstenberg was the CEO of  
14 Boehringer in the United States.

15 Q. And by Boehringer in the United States,  
16 do you mean BIPI?

17 A. I mean all the divisions. The total  
18 company.

19 Q. So was he the CEO of BIC?

20 A. You know, again, I don't know what the  
21 legal aspects were, but he was basically the  
22 overall country manager for the United States.

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1 Q. Including Roxane?

2 A. Including Roxane.

3 Q. Did you report to Mr. Gerstenberg?

4 A. Yes, I did.

5 Q. Was there anyone in between you and Mr.  
6 Gerstenberg in the hierarchy of the corporation  
7 or were you pretty much directly reporting to  
8 him?

9 MR. GASTWIRTH: Objection to form.

10 THE DEPONENT: I reported directly to  
11 Mr. Gerstenberg.

12 BY MR. FAUCI:

13 Q. On the first page in the fourth  
14 paragraph down, can you just read the first  
15 sentence into the record.

16 A. Starting with Shelly's duties?

17 Q. Yes. Thank you.

18 A. Shelly's duties will mainly focus on  
19 the strategic alignment of our ethical  
20 pharmaceutical business in the U.S. and he will  
21 be responsible for the operating result for this  
22 area.

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1 BY MR. FAUCI:

2 Q. Were you an officer at any other -- any  
3 other Boehringer Ingelheim companies besides BIPI  
4 and BIC?

5 MR. GASTWIRTH: Objection to form.

6 THE DEPONENT: No.

7 BY MR. FAUCI:

8 Q. Which company paid your salary?

9 A. I believe it was BIPI that paid my  
10 salary.

11 Q. Did you receive a salary from BIC?

12 A. No.

13 Q. Did you sit on any boards of directors  
14 for Boehringer Ingelheim companies?

15 MR. GASTWIRTH: Objection to form.

16 THE DEPONENT: The only board -- The  
17 only direct position I believe I had was with --  
18 was with Roxane Laboratories.

19 BY MR. FAUCI:

20 Q. Do you know approximately how long you  
21 served on the Roxane board?

22 A. Off the top of my head I can't

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1 remember. It may be a few years, but I can't  
2 remember specifically.

3 Q. Do you remember anyone else who served  
4 on the board?

5 A. Of?

6 Q. Of Roxane.

7 A. Certainly Mr. Gerstenberg.

8 Q. Can you remember anyone else?

9 A. I'm not -- Again, it was not an active  
10 board per se. I think it was more of a legal --  
11 legal entity.

12 Q. What do you mean it wasn't an active  
13 board?

14 A. There -- Again, very -- You know, it's  
15 a number of years ago, so it's hard for me to  
16 remember, but as far as I remember there were  
17 very, very infrequent meetings and it was more to  
18 form than anything else. It wasn't operational  
19 in other words.

20 Q. Do you recall any meetings of the  
21 Roxane board of directors?

22 A. Not specific.

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1 bottom right-hand corner.

2 Do you recognize this document?

3 A. Not specifically.

4 Q. Do you see on the first page it says,  
5 Minutes of the meeting of board of directors,  
6 Boehringer Ingelheim Corporation, October 28,  
7 1998?

8 A. Yes, I do.

9 Q. I'm going to direct your attention to  
10 BIC Juris 0236.

11 A. Okay.

12 Q. Can you please read the first sentence  
13 from the paragraph starting, Mr. Berkle.

14 A. Mr. Berkle explained the reorganization  
15 of the strategetic business unit ethical  
16 pharmaceuticals advising that it now has two  
17 components, one being generic drugs and the other  
18 branded generic drugs.

19 Q. Do you agree that the strategic  
20 business unit ethical pharmaceuticals had two  
21 components, one being generic drugs and the other  
22 branded generic drugs?

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1           A.    I -- A slight variation of that. I  
2    think this refers to the Roxane component of the  
3    strategic business unit. It doesn't refer to the  
4    BIPI component, which is purely branded.

5           Q.    So there was --

6           A.    Really three.

7           Q.    I'm sorry. What do you mean by really  
8    three?

9           A.    Again, this is -- this refers only to  
10   Roxane Laboratories.

11          Q.    Okay.

12          A.    Okay? That's --

13          Q.    And so there was a Roxane Laboratories  
14   component of the business unit?

15          A.    Yes. According to -- According to this  
16   anyway definition.

17          Q.    The third sentence down in the same  
18   paragraph it says, Sales and marketing for  
19   branded generics will report to BIPI  
20   counterparts. Are branded generics, are those  
21   Roxane products?

22          A.    Yes, they were.

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1 Q. Why are Roxane sales and marketing  
2 reporting to their BIPI counterparts?

3 MR. GASTWIRTH: Objection to form.  
4 That's not what this document says.

5 BY MR. FAUCI:

6 Q. Well, I can -- Let's just look at the  
7 sentence. It says, Sales and marketing for  
8 branded generics will report to BIPI  
9 counterparts. Can you tell me what -- what you  
10 think that sentence means?

11 A. Well, I can tell you what the situation  
12 actually was.

13 Q. Okay. That's --

14 A. Okay. And -- And again, because I  
15 certainly can't recall having seen this document,  
16 and I certainly didn't write this document.

17 The situation was that there were  
18 people within the Roxane organization, within the  
19 Roxane business unit, business entity that had  
20 responsibility for the day-to-day operations and  
21 the various functions, including marketing and  
22 sales.

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1           And as I think we talked about  
2           previously in the document, just slightly above  
3           that particular line, there's two components of  
4           the Roxane business, multi-source generic and  
5           branded generic.

6           So for the branded generic products  
7           there was only a few of them. Those people  
8           within the Roxane business entity did report  
9           functionally to designated people within the BIPI  
10          organization, but the day-to-day operations were  
11          still conducted by Roxane people.

12          Q.    Okay. The last sentence of this same  
13          paragraph reads, The contracting and pricing  
14          departments will be combined for ROI and BIPI.  
15          Do you recall if this -- if this happened?

16          A.    This happened really from the  
17          administrative perspective, so that there was --  
18          you know, the actual establishment of pricing or  
19          contracting was done by individuals within the  
20          Roxane business entity, but the processing of the  
21          administration, the submission of prices, were  
22          done by a central unit within -- within BIPI that

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1 instance?

2 A. Absolutely.

3 Q. Couple paragraphs down it says, Shelly  
4 and I -- And this is David Townley writing. He  
5 writes, Shelly and I have talked this -- talked  
6 through this tonight and he suggested that I  
7 approach you directly to request your assistance.

8 Do you recall having a conversation  
9 with Mr. Townley in and around the October 1995  
10 time frame? I recognize it's a long time ago.

11 A. Not -- Not specifically.

12 Q. Do you have any reason to believe you  
13 didn't have a conversation with Mr. Townley as he  
14 references in this e-mail?

15 A. No, I do not.

16 Q. I'm going to read a little bit further.  
17 What we need from you is a clear strategic  
18 outline of overall USA plans with respect --  
19 reference to points one, three and four above to  
20 also include sales casts for the PEP planning  
21 period; i.e., 1996 to 2000.

22 This should be from a total USA

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1 perspective; i.e., BIPI and Roxane combined  
2 strategy. For example, how much Ipratropium UDV  
3 business can Roxane take from BIPI and how do we,  
4 quote, shut out, quote, other non-Bi generics as  
5 far as possible? What does it mean for Roxane to  
6 take Ipratropium business from BIPI?

7 A. You know, again, it's not my language.  
8 You know, I can't tell you specifically what  
9 someone else meant or didn't mean by that. So  
10 again, strategically the two companies would work  
11 together to try to maintain the Ipratropium  
12 business whether it be Atrovent or otherwise  
13 within the Boehringer family of companies.

14 Q. What did you understand Mr. Townley to  
15 mean when he writes this should be from a total  
16 USA perspective, i.e. BIPI and Roxane combined  
17 strategy?

18 MR. GASTWIRTH: Objection to form.

19 THE DEPONENT: You know, I think I just  
20 referred to that. I think -- number one, that  
21 this strategy -- this overall strategy referred  
22 to as the PEP strategy certainly was broader than

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1 Berkle. We are back on the record.

2 BY MR. FAUCI:

3 Q. Mr. Berkle, I've handed you what the  
4 court reporter marked as Exhibit 12. Please take  
5 a moment to familiarize yourself with it.

6 A. Okay.

7 Q. See the first page of this document  
8 appears to be a fax cover sheet?

9 A. Yes.

10 Q. From Ed Tupa to Mr. Shelly Berkle. Do  
11 you see that?

12 A. Yes, I do.

13 Q. Do you recall receiving this document?

14 A. No, I don't.

15 Q. The first paragraph says -- the top of  
16 it, the heading, says, Ipratropium Bromide UDV  
17 generic launch home health care market meeting  
18 summary. Do you see that?

19 A. Yes, I do.

20 Q. And then below that, Roxane  
21 Laboratories represented by Tom Via, Jerry Walsh,  
22 John Powers, Ed Tupa and consultant Mark Pope,

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1 and Boehringer Ingelheim represented by Scott  
2 Richardson, Mike Spitalli and Joe Ashey met to  
3 discuss the approaching generic launch of  
4 Ipratropium Bromide on January 24th.

5 Tom Via, who's he?

6 A. He was in the marketing department at  
7 Roxane Laboratories.

8 Q. Jerry Walsh?

9 A. Jerry was a Roxane employee. I can't  
10 remember his specific title or --

11 Q. We've --

12 A. -- position.

13 Q. Sorry. We've already talked about Mr.  
14 Powers and Mr. Tupa.

15 A. Correct.

16 Q. Consultant Mark Pope, who is he?

17 A. I have no idea. He's a consultant  
18 obviously.

19 Q. Have you ever heard of him?

20 A. I can't recall.

21 Q. And then Boehringer Ingelheim, is that  
22 BIPI?

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1 A. Yes, it is.

2 Q. And they're represented by three people  
3 at this meeting?

4 A. Correct.

5 Q. Why are BIPI personnel at this meeting?

6 A. You know, I think again, you know,  
7 Atrovent was a BIPI drug, the brand -- the patent  
8 would be expiring. It was anticipated that the  
9 two sister companies would work together to best  
10 protect the -- or maintain Atrovent or  
11 Ipratropium business within the Boehringer  
12 family.

13 So I don't think there's anything  
14 negative about that. I think it's only natural  
15 business that companies try to work together to  
16 see how can they maintain the business.

17 Q. The last paragraph, The single latest  
18 factor that will influence the success of this  
19 product is Dey Laboratories. Do you agree with  
20 that?

21 A. Where are you reading from?

22 Q. The very -- First sentence of the very



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1 A. Yes, I do.

2 Q. And we said earlier Mark Pope was  
3 identified as a consultant for Roxane. Do you  
4 recall that?

5 A. Yes, I do.

6 Q. The third paragraph says, Mr. Pope  
7 says, I think it's unrealistic to consider that  
8 there will be anywhere near a reasonable amount  
9 of brand loyalty for this product given the  
10 market dynamics and the nature of competition.  
11 The challenge is to get BIPI to, quote, buy into,  
12 quote, the long term strategic benefits while  
13 relinquishing today's profit dollars and control  
14 of the bulk of the product sales.

15 Would there be any long-term strategic  
16 benefits to BIPI of relinquishing today's profit  
17 dollars?

18 MR. GASTWIRTH: Objection to form.

19 THE DEPONENT: Not to BIPI specific,  
20 but if there is a recognition there's going to be  
21 other generic competition it would be beneficial  
22 to keep the business within the Boehringer

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1 family.

2 BY MR. FAUCI:

3 Q. Beneficial to the whole Boehringer  
4 Ingelheim family?

5 A. Correct.

6 Q. Was there -- Were you aware of any  
7 strategy to give up or relinquish market share of  
8 Atrovent in order to have it moved to Roxane?

9 MR. GASTWIRTH: Objection to form.

10 THE DEPONENT: None that we haven't  
11 already discussed. Again, there had been  
12 discussion on allowing Roxane to preemptively  
13 launch their generic version of Ipratropium  
14 Bromide. And as such you obviously -- Atrovent  
15 would lose some market share when it was still  
16 exclusive.

17 BY MR. FAUCI:

18 Q. But it would be -- that would be  
19 beneficial to the whole BI family?

20 A. Correct.

21 Q. That's all with that document.

22 Moving along. I'm going to show you a

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1 is, but it's not going to be within the context  
2 of this document specifically.

3 MR. FAUCI: That's fine. Let's just  
4 redo this again.

5 BY MR. FAUCI:

6 Q. This strategy costs the innovator  
7 company a lot of money. What do you understand  
8 it to mean that it was the innovator company?  
9 Who do you think that is?

10 A. From a general interpretation of the  
11 word "innovator," innovator to me means the  
12 original branded product. In this case the  
13 original branded product of Ipratropium was  
14 Atrovent which was a BIPI product.

15 Q. And how did the strategy of launching  
16 Ipratropium Bromide cost BIPI a lot of money?

17 MR. GASTWIRTH: Objection to form.

18 BY MR. FAUCI:

19 Q. Let me try that again. Do you agree  
20 that the strategy of launching Ipratropium  
21 Bromide, the timing of the launch, cost BIPI a  
22 lot of money?

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1           A.     Again, in the context that Roxane  
2 preemptively launched Ipratropium prior to any  
3 other generic competitors had a cost from a BIPI  
4 perspective. It allowed sales for the Roxane  
5 product at a lesser price than the branded price  
6 at a time when Atrovent still was patent  
7 protected.

8           Q.     I'm going to move on from this  
9 document.

10           I think we're on Exhibit 19. I'm going  
11 to have the court reporter mark this.

12                     (Exhibit Berkle 019 was marked.)

13           THE DEPONENT:   Okay.

14 BY MR. FAUCI:

15           Q.     Was it your prior testimony, and  
16 correct me if I'm wrong, that -- that your  
17 involvement to the extent you had involvement  
18 with Ipratropium Bromide came around the time of  
19 its launch?

20           MR. GASTWIRTH:   Objection to form.  
21 Misstates the witness' prior testimony.

22           MR. FAUCI:   It's a question about

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1 A. Yes, I did.

2 Q. And did you notice any correct -- any  
3 inaccuracies during that reading?

4 A. Not that I could remember.

5 Q. That's all.

6 I'm going to show you Exhibit 29.

7 (Exhibit Berkle 029 was marked.)

8 MR. GASTWIRTH: And I'll object to the  
9 introduction of that deposition -- prior  
10 deposition transcript as an exhibit to this  
11 deposition.

12 We've got obviously a deposition being  
13 conducted in that case, so I'm not going to allow  
14 for the admissibility of Mr. Berkle's prior  
15 deposition testimony to be used in connection  
16 with the deposition that's occurring today. So  
17 his testimony today will stand for itself.

18 MR. BREEN: The only concern I've got  
19 with that is we've got -- we've got the one day  
20 with this witness that has been scheduled, and if  
21 I'm going to -- if that's what Roxane is going to  
22 do, stand on this not being -- his prior

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1 testimony not being usable in the case, even the  
2 issues are the same and everything else, it may  
3 significantly extend the amount of time I'm going  
4 to need with this witness particularly since this  
5 case has been cross-noticed in the Florida case.

6 So -- And I ask you just to reconsider  
7 that maybe. I don't want to waste this witness'  
8 time, but if I've got to go back and ask him 90  
9 percent of the questions, I think that's really  
10 unnecessary, but if I have to, I'll have to do  
11 it.

12 MR. GASTWIRTH: I'm going to let my  
13 objection stay on the record today and we can  
14 talk after the conclusion of the deposition.

15 MR. BREEN: Right. Because obviously  
16 if I had to do that we're not going to get it  
17 done today and we've only scheduled this  
18 gentleman for one day as of now. So we can work  
19 it out I'm sure, but I just want to make sure  
20 it's clear.

21 MR. GASTWIRTH: I understand. I'm  
22 still objecting to the introduction.

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1 that this document needs to be revoked on  
2 attorney-client or work-product grounds.

3 MR. BREEN: Absolutely. From Ven-a-  
4 Care's perspective the fact that you're doing  
5 that as an accommodation is appreciated. We will  
6 not consider that a waiver or a general waiver of  
7 -- of the matter.

8 MR. FAUCI: Nor will the United States.

9 MS. ROGERS: Or the State of Florida.

10 MR. GASTWIRTH: Thank you.

11 BY MR. FAUCI:

12 Q. So moving back, Mr. Berkle. Do you  
13 recall that around the 1997 time frame there were  
14 discussions about the need to review BIPI and  
15 RLI's contracting and pricing processes?

16 MR. GASTWIRTH: Objection to form. Did  
17 you say 1999?

18 MR. FAUCI: 1997. Intended to say  
19 1997.

20 THE DEPONENT: You know, I don't - I  
21 don't remember the specific time frames. Part of  
22 the difficulty is you've shown me memos

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1 Q. The first page of this is an e-mail.  
2 It's from Dan Gerrity.

3 A. Right.

4 Q. It seems to attach a document about the  
5 pricing policy and procedures. Do you see that?

6 A. Yes.

7 Q. It says, Please review the attached  
8 draft pricing policy and procedure and provide me  
9 any changes you deem appropriate. Do you see  
10 that?

11 A. Yes, I do.

12 Q. And this e-mail is dated May 3rd, 2001.  
13 Do you see that?

14 A. I do.

15 Q. Let's turn to the pricing policy and  
16 procedure document. It says, Scope, this policy  
17 is applicable to wholesale acquisition cost,  
18 average wholesale price, minimum bid price,  
19 direct price for brand products of Boehringer  
20 Ingelheim Pharmaceuticals, Inc. and Roxane  
21 Laboratories.

22 I had to adjust my microphone there.

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1 Was there a single policy applicable to those  
2 prices for brand products of Boehringer Ingelheim  
3 Pharmaceuticals and Roxane Labs?

4 MR. GASTWIRTH: Objection. Form.

5 THE DEPONENT: A single policy?

6 BY MR. FAUCI:

7 Q. Let me rephrase that. It says, This  
8 policy is applicable to various prices for brand  
9 products of Boehringer Ingelheim Pharmaceuticals,  
10 Inc. and Roxane Labs. Do you see that?

11 A. Yes, I do.

12 Q. Does it surprise you that there's a  
13 document out there that says that there's one --  
14 that there's a policy that's applicable to prices  
15 for both companies?

16 MR. GASTWIRTH: Objection. Form.

17 THE DEPONENT: My understanding of this  
18 is that it's applicable to the branded products.  
19 Okay. So BIPI and branded generics of Roxane.

20 BY MR. FAUCI:

21 Q. So you think this pertains to a pricing  
22 policy for Roxane's branded generics and BIPI's

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1 brand products; is that correct?

2 A. I believe so. And, you know, again my  
3 memory isn't a hundred percent, but this was in  
4 May of '01, according to the cover memo -- cover  
5 e-mail --

6 Q. Cover e-mail. Sure.

7 A. -- and I believe this was approaching  
8 the time when we divested of the Roxane branded  
9 generic line.

10 Q. What do you mean you divested of the  
11 Roxane branded generic line?

12 A. The -- Again, if I recall correctly  
13 Viramune, which was under the Roxane label, was  
14 transferred to the BIPI label and then the  
15 palliative care line was in fact divested sold.

16 Q. To who?

17 A. It was initially sold to Elan who then  
18 I know in turn sold it somewhere else. So this  
19 was -- you know, this would have been for a very  
20 short period of time.

21 Q. What was the -- the drug that you said  
22 was transferred to BIPI?

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1 THE DEPONENT: I believe so.

2 BY MR. FAUCI:

3 Q. And do you know if BIPI paid Roxane for  
4 Viramune?

5 MR. GASTWIRTH: Objection. Form. This  
6 is really -- This is outside of context of this  
7 complaint, so --

8 MR. FAUCI: How is it -- Well, I'm not  
9 -- I've got one more question on this.

10 THE DEPONENT: I -- You know, I can't  
11 answer that definitively. I don't believe so,  
12 but I don't know.

13 MR. FAUCI: I'll just state for the  
14 record, Roxane's asserted a cooperate veil  
15 defense in this case and whether or not Roxane  
16 transferred a product to BIPI for fair market  
17 value is squarely within the allegations of the  
18 complaint. But that's all I have on that.

19 BY MR. FAUCI:

20 Q. Right below it it says pricing  
21 approvals. Do you see that?

22 A. Yes.

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1 Q. Recommended prices must be approved in  
2 the following sequence. First, PTC committee.  
3 Second, executive vice president ethical  
4 pharmaceuticals. Is that you?

5 A. Yes, it is.

6 Q. And third, president and CEO of  
7 Boehringer Ingelheim Corporation. Who is that?

8 A. That was Mr. Gerstenberg.

9 Q. Mr. Gerstenberg.

10 A. Right.

11 Q. And so according to this document you  
12 were supposed to approve prices for BIPI brand  
13 products and Roxane branded generics?

14 MR. GASTWIRTH: Objection. Form.

15 THE DEPONENT: It appears to be.

16 BY MR. FAUCI:

17 Q. And so -- and this policy applies to  
18 wholesale acquisition costs?

19 MR. GASTWIRTH: Objection. Form.

20 THE DEPONENT: Yes.

21 BY MR. FAUCI:

22 Q. And average wholesale prices?

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1 MR. GASTWIRTH: Objection.

2 THE DEPONENT: Again, you know, my  
3 primary concern was the wholesale acquisition  
4 cost and then the details in terms of  
5 establishing reference prices was left to others.  
6 BY MR. FAUCI:

7 Q. But you had to approve them?

8 MR. GASTWIRTH: Objection. Form.

9 THE DEPONENT: I can't recall  
10 specifically exactly what I would have approved,  
11 but certainly my focus would be on the WAC.

12 BY MR. FAUCI:

13 Q. When you approve price, what was sent  
14 to you?

15 MR. GASTWIRTH: Objection. Form.  
16 Approve prices for what?

17 BY MR. FAUCI:

18 Q. Any -- This document is saying that Mr.  
19 Berkle recommended prices must be approved in the  
20 following sequence. First, PTC committee.  
21 Second, executive vice president ethical  
22 pharmaceuticals. Was that you, Mr. Berkle?

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1 A. Yes, it was.

2 Q. And this policy is applicable to  
3 wholesale acquisition costs and average wholesale  
4 prices. That's what it says at the top?

5 A. Yes.

6 Q. When you -- If you were to approve a  
7 wholesale acquisition cost or an average  
8 wholesale price, what would be sent to you to  
9 make the decision on whether or not to approve  
10 it?

11 MR. GASTWIRTH: Objection. Form.

12 THE DEPONENT: You know, let me  
13 reiterate that I can't recall exactly what was  
14 sent to me. My focus was on WAC. It would have  
15 been a summary of the information that is listed  
16 under pricing proposals.

17 MR. FAUCI: Can you repeat the answer  
18 for me.

19 (Record was read by the court  
20 reporter.)

21 BY MR. FAUCI:

22 Q. What types of information would be

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1 adjustment.

2 Q. Have you read or seen this before?

3 A. No, I have not.

4 Q. That's all. We're going to do another  
5 document.

6 (Exhibit Berkle 034 was marked.)

7 BY MR. FAUCI:

8 Q. The court reporter has handed you  
9 what's been marked as Exhibit 34. It's a very  
10 lengthy document. Feel free to read it, but I'm  
11 going to direct your attention to specific parts  
12 of it, so just tell me when you feel ready to  
13 have some questions -- have some questions asked.

14 MR. BREEN: Did you already mark this  
15 one?

16 MR. FAUCI: Yep. 34.

17 THE DEPONENT: Okay.

18 BY MR. FAUCI:

19 Q. Do you recognize this document?

20 A. Not specifically.

21 Q. Look at the first page. It appears to  
22 be an e-mail from Fred Duy. Who's he?

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1 A. Fred was a Roxane employee.

2 Q. And it's sent to you, Shelly Berkle?

3 A. Yes, it is.

4 Q. Subject, Roxicodone 15/30mg launch  
5 plan. Do you see that?

6 A. Yes, I do.

7 Q. And then does the attachment to this e-  
8 mail appear to be a launch plan for Roxicodone?

9 A. It certainly appears to be at least a  
10 summary of a launch plan. Highlights.

11 Q. Is Roxicodone a Roxane product?

12 A. Yes, it was.

13 Q. Second sentence of the e-mail, The  
14 strategy is essentially what you saw in  
15 Tarrytown. What's Tarrytown?

16 A. It's -- Tarrytown is a town in New York  
17 State close -- just across the border from  
18 Connecticut.

19 Q. What brought you to Tarrytown?

20 A. I'm sorry?

21 Q. What brought you to Tarrytown?

22 A. Well, there's a conference that was

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1 utilized frequently for meetings by -- by the  
2 BIPI people, BIPI/Roxane people.

3 Q. Do you recall -- The strategy is  
4 essentially what you saw in Tarrytown. Do you  
5 recall being exposed to strategies relating to a  
6 launch document in Tarrytown?

7 A. I can't -- I can't remember  
8 specifically that meeting. You know, certainly I  
9 was at multiple meetings over the years in  
10 Tarrytown, but I can't remember the details.

11 Q. It goes on to say that, It--I think the  
12 strategy--has been updated and expanded with  
13 specific tactics by Doug Bierl with input from  
14 lots of people here and in Ridgefield. Who's  
15 Doug Bierl?

16 A. I haven't got a clue.

17 Q. What's Ridgefield?

18 A. Ridgefield is the town -- location of  
19 BI Pharmaceuticals.

20 Q. Where was Roxane?

21 A. In Columbus, Ohio.

22 Q. Ridgefield means BIPI?

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1 A. It means BIPI, BIC.

2 Q. BIC. Why are people in Ridgefield  
3 updating and expanding a strategy for the launch  
4 of a Roxane product?

5 MR. GASTWIRTH: Objection. Form.

6 THE DEPONENT: This goes along with  
7 some of the memos you've shown me before.  
8 Roxicodone was a branded generic and, therefore,  
9 there was some supervisory role that some -- a  
10 few BIPI people played. But again, the launch  
11 plan, as you see here, was put together by Roxane  
12 employees.

13 BY MR. FAUCI:

14 Q. It says, We expect approval by the user  
15 fee deadline, August 29th. What does that mean?

16 A. I assume that refers to the FDA  
17 approval.

18 Q. FDA approval -- The FDA approval of the  
19 drug?

20 A. Correct.

21 Q. Okay. Last sentence of that paragraph,  
22 If you can fit it into your schedule, we would be

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1 happy to present the launch plan to you and  
2 whoever you think is appropriate in Ridgefield.  
3 Do you recall if this launch plan was presented  
4 to you in Ridgefield?

5 A. I do not recall.

6 Q. Do you recall if you read the launch  
7 plan?

8 A. I don't recall specifically if I did or  
9 didn't.

10 Q. Do you recall whether you approved the  
11 launch of the Roxicodone product?

12 MR. GASTWIRTH: Objection. Form.

13 THE DEPONENT: The way you've said it  
14 is basically we put together a data package for  
15 FDA approval, which meant that the decision was  
16 that we would move ahead once approved to market  
17 the drug.

18 So this would have been not just a sole  
19 decision on my part. Okay. This would have  
20 involved Gerstenberg, Russillo, other people.  
21 Medical department, regulatory department.

22 BY MR. FAUCI:

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1 Q. Do you recall if you were one of the  
2 people who gave approval for marketing the  
3 Roxicodone product?

4 MR. GASTWIRTH: Objection. Form.

5 THE DEPONENT: I -- I believe I  
6 certainly was a part of the senior management  
7 team that -- that would have heard the  
8 recommendation and would have agreed to -- to  
9 marketing it.

10 BY MR. FAUCI:

11 Q. I direct your attention to page 23.  
12 It's Shaffer 001474. The heading is Market  
13 Situation, Market Characteristic Summary.

14 A. Got it.

15 Q. Do you see at the bottom it says price  
16 and reimbursement driven. Do you see that?

17 A. I see that.

18 Q. At the top it's market characteristics  
19 summary. Do you see that?

20 A. Yes.

21 Q. Let's break that down. What does it  
22 mean for something to be price driven?

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1           And in this case, as far as I can see,  
2     it -- it allowed -- it was a competitive pricing  
3     versus, you know, multiple tablets of a five-  
4     milligram Oxycodone on the market. So...

5           Q.     The fact that the suggested AWP for the  
6     Roxicodone five-milligram 100s was twice as high  
7     as the WAC, that wouldn't have jumped out at you?

8           MR. GASTWIRTH:   Objection. Asked and  
9     answered.

10          THE DEPONENT:   Yeah. I mean, I said,  
11     you know, you have to take that in context of  
12     what the competitive environment was.

13     BY MR. FAUCI:

14          Q.     Mr. Berkle, thank you very much for  
15     coming here today.

16          Oh, I guess I have one more question  
17     for you. I'm sorry.

18          A.     Good thing I didn't say you're welcome.

19                   (Exhibit Berkle 036 was marked.)

20          THE DEPONENT:   Okay.

21     BY MR. FAUCI:

22          Q.     Who's Christine Ferrara?

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1 A. Chris was a BIPI employee and was  
2 involved in the contract pricing department.

3 Q. Do you recognize this e-mail?

4 A. No, I don't specifically.

5 Q. Do you see that it's an e-mail --  
6 there's two e-mails. One's from Christine  
7 Ferrara dated August 23rd to Fred Duy. Do you  
8 see that?

9 A. Yes, I do.

10 Q. The subject is price?

11 A. Yes.

12 Q. Dear Fred, Shelly assigned the  
13 approval, but Werner won't be in until tomorrow  
14 at which time I expect that he will review and  
15 hopefully approve as well, regards, Chris. Do  
16 you see that?

17 A. Yes, I do.

18 Q. And then above it. The top e-mail  
19 again is from Christine Ferrara to Fred Duy.  
20 It's dated August 24th. Do you see that?

21 A. Yes, I do.

22 Q. It says, Attach, Roxicodone WAC AWP

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1 proposal.doc. Do you see that?

2 A. Yes.

3 Q. Fred, I have received verbal  
4 confirmation that the attached pricing has been  
5 approved by Shelly and Werner. Do you see that?

6 A. Yes, I do.

7 Q. Does this refresh your --

8 A. No. I mean, I assume it is what it is,  
9 but I certainly don't remember.

10 Q. You don't have any reason to think that  
11 you didn't, in fact, approve the Roxicodone WAC  
12 AWP proposal?

13 MR. GASTWIRTH: Objection. Form.

14 THE DEPONENT: I have no reason to not  
15 believe that.

16 MR. FAUCI: For real this time I'll say  
17 thank you very much for your testimony. I have  
18 no further questions at this time. I reserve the  
19 right to ask questions after Mr. Gastwirth if, in  
20 fact, Mr. Gastwirth asks questions.

21 MR. GASTWIRTH: Off the record for a  
22 minute.

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1 tenure?

2 MR. GASTWIRTH: Objection. Form.

3 THE DEPONENT: Werner Gerstenberg.

4 BY MR. BREEN:

5 Q. And who was the president of BIPI  
6 during your tenure?

7 A. There was no president of BIPI.

8 Q. Then who was the chief executive  
9 officer that ran the company?

10 A. Again, my position I believe was the  
11 highest level position within BIPI reporting to  
12 the present CEO of BIC.

13 Q. Okay. So all and all Mr. Gerstenheimer  
14 was your boss?

15 A. Mr. Gerstenberg.

16 Q. Gerstenberg. I apologize.

17 Mr. Gerstenberg was your boss?

18 A. Correct.

19 Q. Okay. Now, let's talk a little bit  
20 more about Roxane. I've heard your testimony  
21 today in response to the Department of Justice's  
22 questions, and after going back through the



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1 deposition that we took some time ago, I got -- I  
2 gathered a certain impression. I'm going to  
3 state that to you and tell me -- I want you to  
4 tell me if I'm correct or not.

5 When it came to branded pharmaceuticals  
6 being marketed by Boehringer Ingelheim's U.S.  
7 operations, you generally had some  
8 responsibilities for the sales and marketing  
9 aspects?

10 MR. GASTWIRTH: Objection. Form.

11 THE DEPONENT: For the -- You're  
12 talking about the branded business within BIPI?  
13 BY MR. BREEN:

14 Q. I'm talking about the branded business  
15 in general.

16 MR. GASTWIRTH: Objection. Form.

17 THE DEPONENT: The --

18 MR. GASTWIRTH: I mean, there are --

19 MS. ROGERS: Please don't make speaking  
20 objections.

21 THE DEPONENT: Let me -- Let me just  
22 state that throughout my tenure I was responsible

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1 for marketing -- sales and marketing of BIPI  
2 branded products. For Roxane branded products I  
3 had responsibility for certain periods of time  
4 during my tenure.

5 As an example, after year 2000 I had no  
6 involvement whatsoever. Oh, I'm sorry, I  
7 shouldn't say that. Let me rescind that comment.  
8 That after 2000 I had no involvement with Roxane  
9 multi-source business whatsoever. I already  
10 stated in my previous testimony that sometime  
11 after 2000 the Roxane branded business  
12 disappeared.

13 BY MR. BREEN:

14 Q. That's because the Roxane corporate  
15 entity was turned into a manufacturing entity?

16 MR. GASTWIRTH: Objection. Form.

17 THE DEPONENT: The -- Certainly the  
18 physical company was a manufacturing site. The  
19 Roxane products were combined together with the  
20 Ben Venue products under the leadership of Tom  
21 Russillo in terms of relative to the marketing  
22 and sales and product development, sorry. Also

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1 product development.

2 BY MR. BREEN:

3 Q. And about when was that in 2000?

4 A. I don't remember the specific dates.

5 Q. Do you recall if it was earlier or  
6 later in the year?

7 A. You know what, I don't even want to  
8 hazard to guess.

9 Q. Why don't you take a look at Exhibit 32  
10 -- or 35 which -- What happened to the originals?

11 A. Yeah. It's right here.

12 Q. Thank you.

13 A. Okay.

14 Q. This is dated August 22nd, 2000.

15 A. Right.

16 Q. And this is the one where you and Mr.  
17 Gerstenberg are approving Roxicodone prices. Do  
18 you see that?

19 A. Yes, I do.

20 MR. GASTWIRTH: Objection. Form.

21 BY MR. BREEN:

22 Q. Is there any doubt in your mind that

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1 what Exhibit 35 is is a document that indicates  
2 that you and Mr. Gerstenberg were at least being  
3 asked to approve Roxicodone prices?

4 A. I think I testified to that already.

5 Q. Okay. So does this help refresh your  
6 recollection as to whether or not by at least  
7 August 22nd, 2000 Roxane -- whether or not  
8 Roxane's drug products had been combined with Ben  
9 Venue?

10 MR. GASTWIRTH: Objection. Form.

11 THE DEPONENT: You know, again, I -- I  
12 can't remember. It's just too long ago and  
13 there's too many things that have occurred in my  
14 -- my work experience that really this was such a  
15 -- you know, disappeared from my importance that,  
16 you know, I just can't remember the details.

17 BY MR. BREEN:

18 Q. Well, do you have -- do you know  
19 whether or not -- Well, strike that.

20 Were you involved in any leadership  
21 capacity in the combining of Roxane and Ben  
22 Venue's products?

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1 responsibility for setting prices was not  
2 management responsibility at Roxane?

3 MR. GASTWIRTH: Objection. Form.  
4 Objection. Misstates this witness' prior  
5 testimony as well as my prior question of the  
6 witness.

7 BY MR. BREEN:

8 Q. All right. Let me restate the  
9 question. The fact of the matter is you did from  
10 time to time exercise some managerial  
11 responsibility with respect to Roxane's  
12 operations, at least in the price setting area,  
13 didn't you?

14 MR. GASTWIRTH: Objection. Form.

15 THE DEPONENT: For a period of time for  
16 the branded generics I -- I approved what was  
17 recommended by Roxane management within the  
18 Roxane entity.

19 BY MR. BREEN:

20 Q. All right. So let me ask the question  
21 so I can overcome counsel's objection like we did  
22 earlier. If I ask you if you ever had any

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1 management responsibility at Roxane, would your  
2 answer be what you just said?

3 MR. GASTWIRTH: Objection. Form.

4 BY MR. BREEN:

5 Q. Let me ask the question. Did you ever  
6 have any managerial responsibility at Roxane?

7 MR. GASTWIRTH: Objection. Form. He's  
8 -- He's answered this question a number of times.

9 MR. BREEN: Okay. If it's an asked and  
10 answered objection, that's one thing, but if  
11 you're objecting to form I'm going to ask it  
12 until I get it right.

13 MR. GASTWIRTH: He's answered the  
14 question. He said he's had no managerial  
15 responsibility over Roxane. He had no day-to-day  
16 operational responsibility over Roxane.

17 MR. BREEN: Let's go back because,  
18 Counsel, you're misstating his testimony.

19 MR. GASTWIRTH: Okay.

20 BY MR. BREEN:

21 Q. Setting pricing is a managerial  
22 responsibility, isn't it?

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1 MR. GASTWIRTH: Let me hear that  
2 question back, please. Thank you.

3 (Record was read by the court  
4 reporter.)

5 MR. GASTWIRTH: Which company are you  
6 speaking of?

7 MR. BREEN: Roxane.

8 THE DEPONENT: I was not involved in  
9 the setting of Roxane multi-source products,  
10 pricing for multi-source products. I was  
11 involved for -- for a period of time approving  
12 prices that were recommended by Roxane's senior  
13 managers for the branded generic products.

14 BY MR. BREEN:

15 Q. For Roxane, correct?

16 A. For Roxane.

17 Q. And that was a management function,  
18 wasn't it?

19 MR. GASTWIRTH: Objection. Form.

20 THE DEPONENT: It was not a day-to-day  
21 operational function. It was an occasional  
22 responsibility.

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1 Q. Were you -- Was that a management  
2 function, sir?

3 MR. GASTWIRTH: Objection. Asked and  
4 answered.

5 BY MR. BREEN:

6 Q. Was that a management function, sir?

7 MR. GASTWIRTH: Objection. Asked and  
8 answered. You are being argumentative with this  
9 witness.

10 MR. BREEN: No. You're being -- You're  
11 being -- You are being totally inappropriate,  
12 Counsel. I am cross-examining this witness based  
13 upon your questions. Now, we can stop and we can  
14 we redo this deposition at another time and I'll  
15 let the judge rule on this, but he'll let me get  
16 an answer to this question. I'll guarantee you.

17 MR. GASTWIRTH: I'll let you get a  
18 fourth answer to this question.

19 THE DEPONENT: I will repeat myself. I  
20 was not involved in the establishment of prices  
21 for the multi-source business. I was involved in  
22 approving prices for branded drugs, Roxane

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1 branded generic drugs, which were recommended by  
2 senior management at Roxane. If that's how you  
3 define managerial responsibility, then that's  
4 what it is.

5 BY MR. BREEN:

6 Q. Thank you. And with respect to what  
7 you just said you did, with respect to branded  
8 drug prices at Roxane, who made the decision as  
9 to when you would and when you would not  
10 participate managerially with respect to Roxane  
11 prices?

12 MR. GASTWIRTH: Objection. Form.

13 THE DEPONENT: You know, I think we  
14 spent some time at looking at process, and  
15 particularly pertinent to Roxicodone, and I think  
16 we saw that the recommended price was asked for  
17 approval by myself and Mr. Gerstenberg.

18 BY MR. BREEN:

19 Q. Okay. So you and Gerstenberg decided  
20 when you would and when you would not participate  
21 in Roxane pricing decisions, correct?

22 A. For --

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1 MR. GASTWIRTH: Objection. Form.

2 THE DEPONENT: For branded generics.

3 BY MR. BREEN:

4 Q. All right. Could you and Mr.  
5 Gerstenberg have easily decided that you would  
6 exercise some responsibility for multi-source  
7 products?

8 MR. GASTWIRTH: Objection. Form.

9 THE DEPONENT: Certainly I could not.

10 BY MR. BREEN:

11 Q. Could Mr. Gerstenberg?

12 A. As country manager, I can't speculate  
13 as to what he could or could not do. I can't  
14 answer for Mr. Gerstenberg.

15 Q. All right. So what circumstances  
16 existed that permitted Mr. Gerstenberg and you to  
17 managerially decide when you would participate in  
18 the branded pricing actions of Roxane but not  
19 participate in the multi-source pricing?

20 MR. GASTWIRTH: Objection. Form.

21 Managerially decided is your term, not this  
22 witness'.

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1                   THE DEPONENT: Yeah. You know, there  
2 was a procedure that was established for branded  
3 -- for BIPI brands and for Roxane branded  
4 generics that stated that I would approve and Mr.  
5 Gerstenberg would approve.

6 BY MR. BREEN:

7           Q. And who established that procedure?

8           A. That was a recommendation by a  
9 committee.

10          Q. And the committee was made up of whom?

11          A. People from BIPI and from Roxane.

12          Q. And when was that?

13          A. You know, again, if we looked back at  
14 the memos you'd be more definitive in terms of  
15 the timing. When was that? That was around,  
16 what, '99, 2000, something like that.

17          Q. And the committee's recommendations  
18 were made to whom?

19          A. I think you're being redundant here.  
20 Did I not already state that the recommendations  
21 were made based on the memos I've seen to myself  
22 and to Mr. Gerstenberg for branded generics.

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